



cologuard[®]

PATIENT GUIDE

INDICATION FOR USE


Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by diagnostic colonoscopy. Cologuard is indicated to screen adults of either sex, 45 years or older, who are at typical average-risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals.

To report any adverse effects from using this kit, or if you need assistance, please call us at 1-844-870-8870. We are available 24 hours a day, 7 days a week to answer your questions.

**EXACT
SCIENCES**

www.cologuardtest.com
Rx Only



 **Exact Sciences**
Madison, WI USA

LBL-10033rev8

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CONTRA-INDICATIONS

Cologuard is intended for use with patients, age 45 years and older, at average risk who are typical candidates for CRC screening.

Cologuard was not clinically evaluated for the following types of patients:

- Patients with a history of colorectal cancer, adenomas, or other related cancers.
- Patients who have had a positive result from another colorectal cancer screening method within the last 6 months.
- Patients who have been diagnosed with a condition that is associated with high risk for colorectal cancer. These include but are not limited to:
 - Inflammatory Bowel Disease (IBD)
 - Chronic ulcerative colitis (CUC)
 - Crohn's disease
 - Familial adenomatous polyposis (FAP)
 - Family history of colorectal cancer
- Patients who have been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary non-polyposis colorectal cancer syndrome (HNPCCC or Lynch Syndrome), Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis.

COLOGUARD WARNINGS AND PRECAUTIONS

The performance of Cologuard has been established in a cross-sectional study (i.e., single point in time). Programmatic performance of Cologuard (i.e., benefits and risks with repeated testing over an established period of time) has not been studied. Performance has not been evaluated in adults who have been previously tested with Cologuard. Non-inferiority or superiority of Cologuard programmatic sensitivity as compared to other recommended screening methods for CRC and AA has not been established.

- The clinical validation study was conducted in patients 50 years of age and older. ACS Guidelines recommend screening begin at age 45. Cologuard performance in patients ages 45-49 was estimated by sub-group analysis of near-age groups.
- CRC screening guideline recommendations vary for persons over the age of 75. The decision to screen persons over the age of 75 should be made on an individualized basis in consultation with a healthcare provider. Cologuard test results should be interpreted with caution in older patients as the rate of false positive results increases with age.
- A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Patients with a negative Cologuard test result should be advised to continue participating in a colorectal cancer screening program with another recommended screening method. The screening interval for this follow-up has not been established.
- Cologuard may produce false negative or false positive results. A false positive result occurs when Cologuard produces a positive result, even though a colonoscopy will not find cancer or precancerous polyps. A false negative result occurs when Cologuard does not detect a precancerous polyp or colorectal cancer even when a colonoscopy identifies the positive result.

COLOGUARD WARNINGS AND PRECAUTIONS

- Patients should not provide a sample for Cologuard if they have diarrhea or if they have blood in their urine or stool (e.g., from bleeding hemorrhoids, bleeding cuts or wounds on their hands, rectal bleeding, or menstruation).
- To ensure the integrity of the sample, **the laboratory must receive the patient specimen within 72 hours of collection.** Initiate the return process **within a day of collecting your sample** to allow enough delivery time. Refer to the shipping instructions provided in this box, or ask your prescriber, for more information.
- Patients should be advised of the caution listed in the Cologuard Patient Guide. Patients should **NOT** drink the preservative liquid.
- The risks related to using the Cologuard Collection Kit are low, with no serious adverse events reported among people in a clinical trial. Patients should be careful when opening and closing the lids to avoid the risk of hand strain.

HOW THE COLOGUARD COLLECTION KIT WORKS

Your healthcare provider has ordered Cologuard to screen for colorectal cancer and precancer.

Cologuard is a screening test that uses a stool sample (your bowel movement) to detect colorectal cancer and precancer. Every day, your colon sheds cells that line the colon. As part of this process, normal cells along with abnormal cells from precancer or cancers are shed into the colon. Your stool picks up those cells as it passes through your colon. Cologuard is designed to detect the DNA and hemoglobin (blood) released from these abnormal cells in your stool.

The Cologuard collection kit is used to collect your stool sample. After you collect your stool sample following the instructions in this Patient Guide, the collection kit will be delivered to a lab. The lab will test your stool sample and send the results to your healthcare provider. Your provider will contact you with the test results.

Note: You are not required to change your diet or medications to use this screening test.

HOW DO I STORE THE COLOGUARD COLLECTION KIT WHEN IT ARRIVES?

You can store your kit until you are ready to use it.

- Store at room temperature.
- Keep away from heat and direct sunlight.
- Keep out of the reach of children.

WHAT DOES THE COLOGUARD TEST RESULT MEAN?

Your healthcare provider will talk with you about your results.
The test result can be **Positive, Negative** or **No result obtained**.

WHAT DOES A POSITIVE RESULT MEAN?

- A Positive result means the test detected abnormal DNA and/or blood that could be caused by precancer or cancer in the colon.
- The test can also have a Positive result that is incorrect (false positive). This means the test result is Positive, but no cancer or precancer is actually present.
- Any Positive result should be followed by a colonoscopy.
- Talk about your test result with your healthcare provider to find out if additional testing is needed.

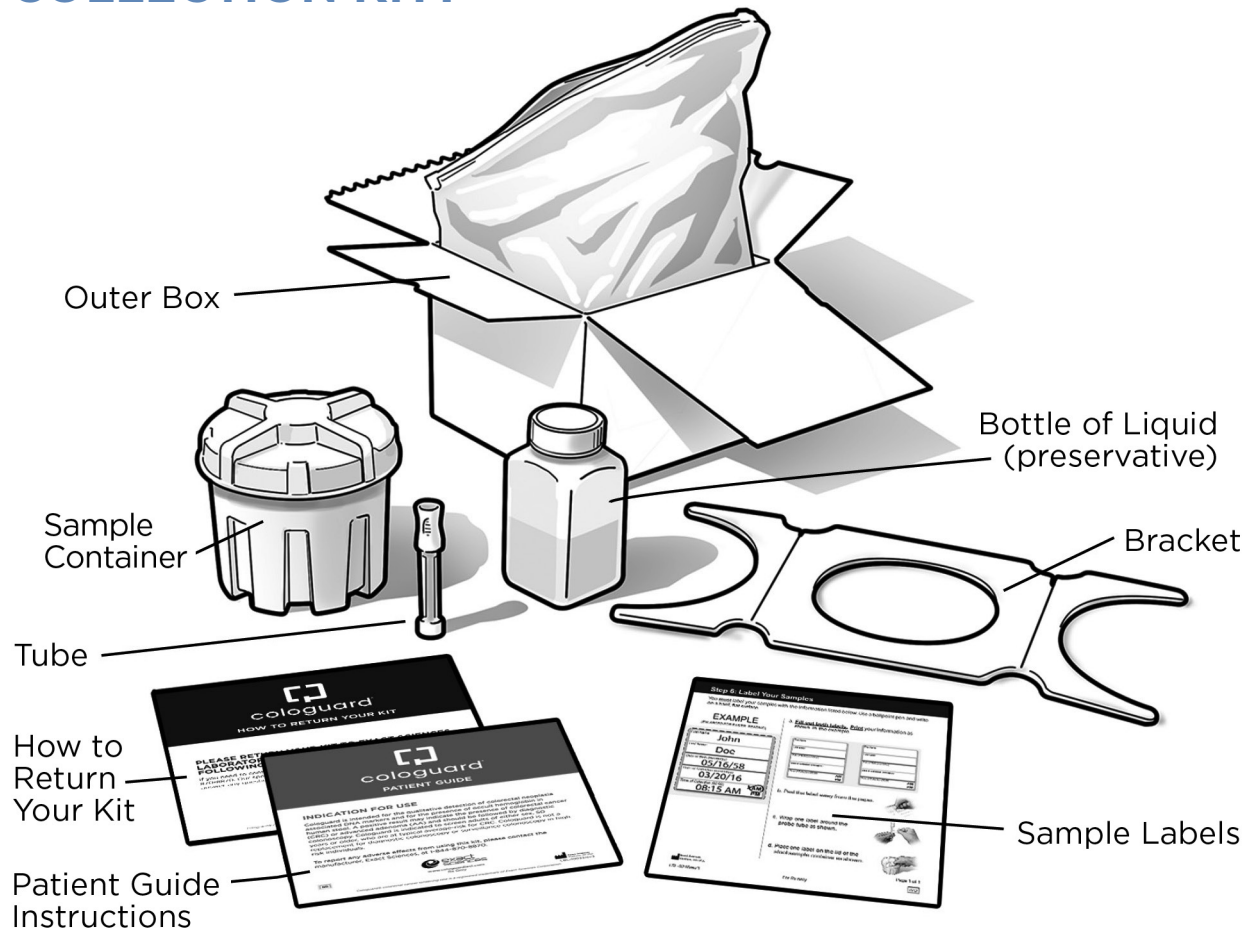
WHAT DOES A NEGATIVE RESULT MEAN?

- A Negative test result means the test did not detect abnormal DNA and/or blood in the sample.
- The test can also have a Negative result that is incorrect (false negative). This means the test result missed a potential cancer or precancer. For that reason, it is recommended that you schedule regular screenings.
- Talk to your healthcare provider about your test result. Your provider will recommend a screening schedule that is best for you.

WHAT DOES NO RESULT OBTAINED MEAN?

- A “No Result Obtained” means the test was not able to provide a result.
- If this happens, your healthcare provider will talk with you about the next steps. For example, you may be asked to provide another stool sample to test.

WHAT IS INSIDE THE COLOGUARD COLLECTION KIT?



- The bottle of liquid contains a preservative (less than 10% EDTA in Tris buffered solution).
- The tube contains a 10% albumin in Tris buffered detergent solution with an antimicrobial agent.

WHO SHOULD USE COLOGUARD?

Cologuard is intended for people who are typical candidates for colorectal cancer screening, which include:

- Men and women 45 years or older
- At average risk for colorectal cancer

IS COLOGUARD RIGHT FOR YOU?

Talk with your healthcare provider about using Cologuard if any of the following apply to you:

- A history of colorectal cancer, adenomas, or other related cancers.
- Had a positive result from another colorectal cancer screening method within the last 6 months.
- Been diagnosed with a condition that is associated with high risk for colorectal cancer. These include but are not limited to:
 - Inflammatory Bowel Disease (IBD)
 - Chronic ulcerative colitis (CUC)
 - Crohn's disease
 - Familial adenomatous polyposis (FAP)
 - Family history of colorectal cancer
- Been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary non-polyposis colorectal cancer syndrome (HNPCCC or Lynch Syndrome), Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, Familial Hyperplastic Polyposis.

CAUTION



Caution

- **Do not drink the bottle of preservative liquid.**
- **Do not let the liquid touch your skin or eyes.**
- If the liquid touches your skin or eyes, wash the area with water.

RISKS

The risks related to using the Cologuard collection kit are low. No serious adverse events were reported among 10,023 people in a clinical trial.

- Opening or closing the lids of items in the kit may be difficult for some people.
 - Be careful when opening and closing the lids to avoid the risk of hand strain.
 - Close all sample containers tightly.
- Using this kit requires sitting down on the toilet and standing up from the toilet.
 - Have someone who can help you if needed.
- There is a chance that a stool sample sent to the lab may have no result.
 - If this happens, you will be contacted. You may be asked to provide another sample.

WHAT SHOULD I KNOW BEFORE USING THE COLOGUARD COLLECTION KIT?



Only remove the items you need to collect your sample following the steps in this guide.

- **Leave the plastic bag inside the box – do not remove.** The box, zippered bag, and white tray inside the bag will be used to return your sample.
- Use the collection kit before the expiration date printed on the side of the box.
- **Your stool sample should be no larger than the bottle of liquid included in the box.**
- Avoid getting urine in the container when collecting your stool sample.
 - Empty your bladder as much as possible, before collecting your stool sample.
- Avoid getting toilet paper or other materials in the container when collecting your stool sample.

WHAT SHOULD I KNOW BEFORE USING THE COLOGUARD COLLECTION KIT? CONTINUED

- **The lab must receive your sample promptly.**
 - Collect a sample when you can return it within a day of collection. Make sure that a Sunday or a holiday will not delay your return.
 - Refer to your return instructions for detailed information on how to return your kit.
- You are not required to change your diet or medications to use this screening test.

When you're ready to collect your sample with the Cologuard collection kit, our video will help you through each step. Go to the following website for more information:

www.cologuardtest.com/already-ordered-cologuard

WHEN SHOULD I NOT USE THE COLOGUARD COLLECTION KIT?

Certain conditions may cause an incorrect test result or no result.

Do **not** use this kit to collect a stool sample if you have:

- Bleeding hemorrhoids
- Bleeding cuts or wounds on your hands
- Rectal bleeding
- Menstrual period
- Diarrhea (abnormal bowel/stool consistency)

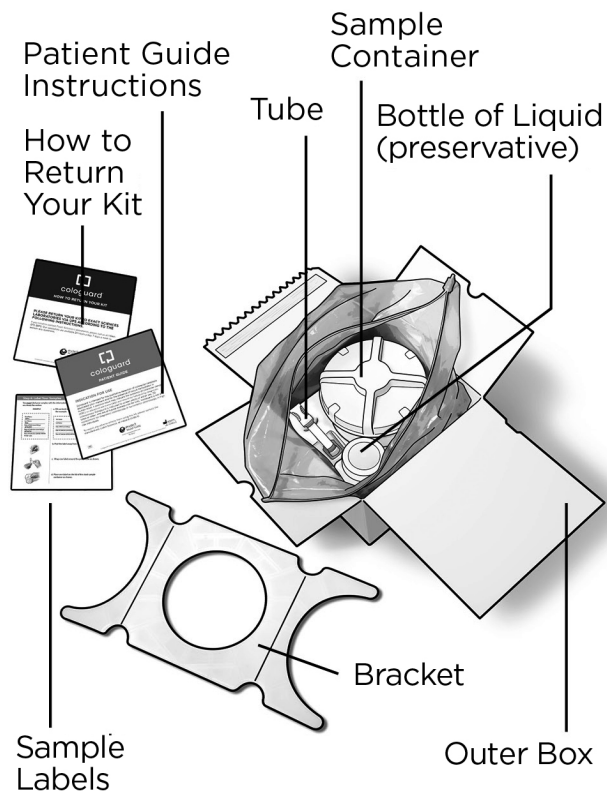
STEP 1: CHECK THE EXPIRATION DATE AND THE KIT

Check your kit to make sure the kit has not expired and you have all the parts of the kit.



- a. Locate the expiration date on the outside of the box.
- b. Use the kit before the expiration date printed on the outside of the box.
 - If the date has passed, do **not** collect your sample. Refer to your return instructions; use the contact information provided to request a new kit.

STEP 1 CONTINUED



Leave the plastic bag and white tray inside the box.

c. Check the items in your box and make sure you have the following:

- Bracket
- Sample container
- Tube
- Bottle of Liquid (preservative)
- Sample labels
- Patient Guide Instructions
- How to Return Your Kit

If any items are missing from your kit, do **not** use the kit. Use the contact information provided to request a new kit.

d. If all items are included in your kit, your kit is ready to use.

Follow the next steps when you feel ready to have a bowel movement.

STEP 2: PREPARE TO COLLECT THE STOOL SAMPLE

Follow these steps in your bathroom to set up the bracket and sample container.



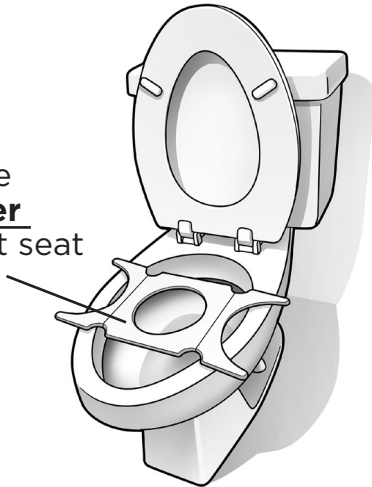
a. Decide the best time to collect a stool sample.

- Follow these steps when you feel ready to have a bowel movement.
- Collect your sample on a day when you can return it promptly.
 - **Refer to your return instructions.**
- Do **not** collect a stool sample if you have:
 - Bleeding hemorrhoids
 - Bleeding cuts or wounds on your hands
 - Rectal bleeding
 - Menstrual period
 - Diarrhea

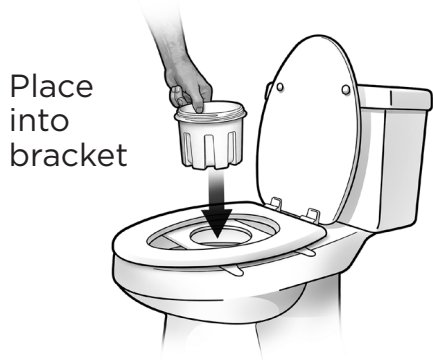
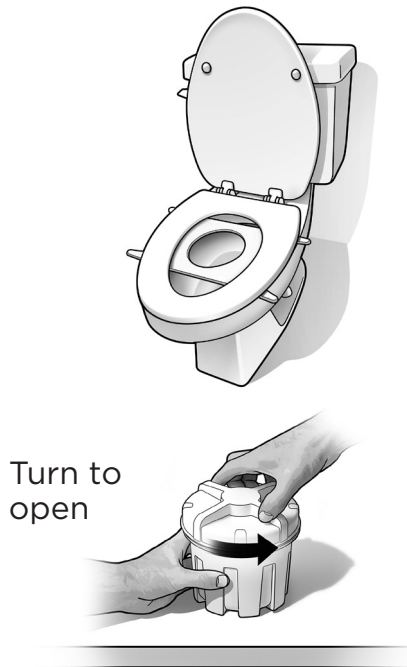
STEP 2 CONTINUED



Place under toilet seat



- b. Remove the bracket from the box and unfold the sides of the bracket.
- c. Raise the toilet lid **and** seat.
- d. Place the bracket on the toilet as shown.
- Place the bracket toward the back of the toilet.



- e. Lower the toilet seat onto the bracket.
- The entire opening of the bracket should be visible.
- f. Lift the sample container out of the box and place on a hard, flat surface.
- g. Turn the container lid and unscrew it.
- If the lid sticks, try pushing down or holding the container between your knees to secure it, while turning the lid.
- i. Set the container lid aside.
- i. Place the container into the top of the bracket.

STEP 3: COLLECT THE STOOL SAMPLE

Make sure you have help if you have trouble sitting and standing when using the toilet.



a.

a. Sit on the toilet and have a bowel movement in the sample container.

- **Your stool sample should be no larger than the bottle of liquid included in the box.**
- **Try to keep urine from going into the container.**
- **Do not put toilet paper or other items into the container.**

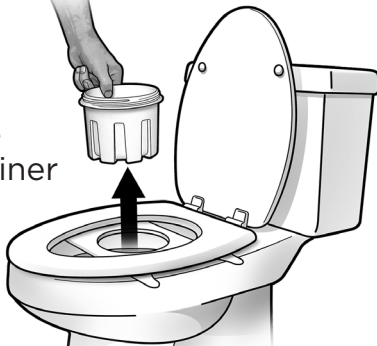
b. When your bowel movement is complete, stand up.

c.

c. Lift the sample container from the bracket and set the container on a flat, stable surface.

- **Leave the container open.**

Leave
container
open





d.

d. Remove the bracket from the toilet.

- The bracket can be recycled or thrown in the trash.



e.

e. Finish using the bathroom if needed.

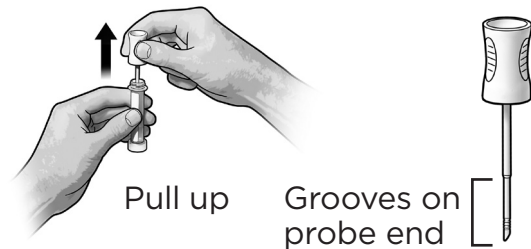
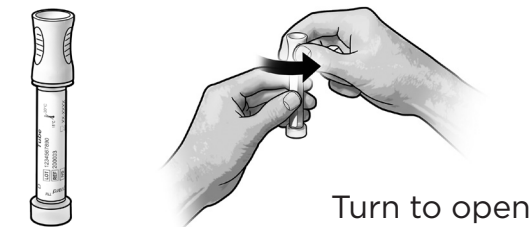
- Follow the rest of the steps in this guide **immediately** after collecting your stool sample.

IMPORTANT: Complete the next step **before** you close the container.

NEXT PAGE 

STEP 4: SCRAPE THE STOOL SAMPLE

You must scrape the stool sample with the probe from the tube to get another small sample for the Cologuard test.



a. Lift the tube out of the box.

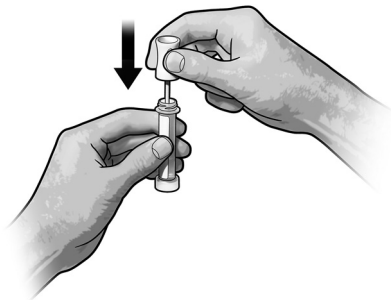
b. Turn the white tube cap and unscrew it.

c. Pull the probe from the tube.
• You may have to pull hard.

d. Scrape the surface of your stool sample until the end of the probe has stool on it.
• Your stool sample may look different from the stool sample pictured.
• You only need to cover the grooves on the probe with stool. **DO NOT FILL TUBE WITH STOOL.**

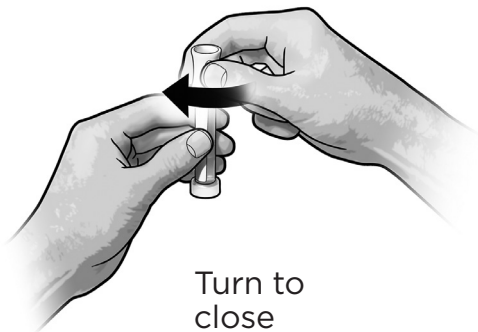


Stool
on probe



e.

e. Place the probe back into the open end of the tube.



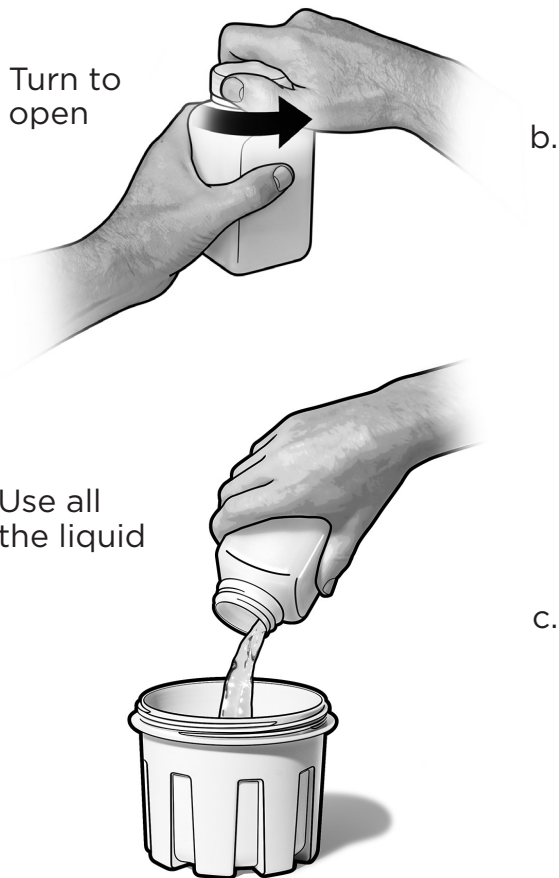
f.

f. Turn the cap to close.

g. Set the tube aside.
Note: Do not place the tube into the stool container.

STEP 5: PREPARE STOOL SAMPLE CONTAINER FOR RETURN

The stool sample must have the preservative poured onto it to make sure the lab can test it. Then, the container must be closed tightly for return.



- a. Lift the bottle of liquid preservative out of the box.
- b. Hold the bottle and turn the cap to unscrew it.



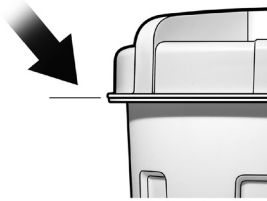
Caution

- Do **not** drink the liquid.
 - If the liquid from the bottle touches your skin or eyes, wash with water.
- c. Pour **ALL** the liquid in the bottle into the container with the stool.
 - The empty bottle and cap can be recycled or thrown in the trash.

Turn to
close tight



Tight seal
Correct!



Lid with gap
Wrong:
*loosen and
tighten again*



d. Hold the sample container on a hard, flat surface.

e.

e. Place the lid on top of the container.

- Make sure the lid is straight so it will close tightly.

f.

f. Turn the lid to tighten until it does not tighten anymore.

- Note: If the lid is not on correctly, liquid could leak out of the container.

STEP 6: LABEL YOUR SAMPLES

You **must** label your samples so the lab can identify them. For best results fill out the labels, as indicated below, before you apply them to the containers. Use a ballpoint pen and write on top of a hard, flat surface.

Step 6: Label Your Samples

You **must** label your samples with the information listed below. Use a ballpoint pen and write on a hard, flat surface.

EXAMPLE
(ENLARGED FOR EASIER READING)

First Name	John
Last Name	Doe
Date of Birth (mm/dd/yy)	05/16/58
Date of Collection (mm/dd/yy)	03/20/16
Time of Collection (00:00)	08:15 AM AM

a. Fill out **both** labels. **Print** your information as shown in the example.

First Name	Last Name
Date of Birth (mm/dd/yy)	Date of Birth (mm/dd/yy)
Date of Collection (mm/dd/yy)	Date of Collection (mm/dd/yy)
Time of Collection (00:00)	Time of Collection (00:00)

b. Peel the label away from the paper.

c. Wrap one label around the probe tube as shown.

d. Place one label on the lid of the stool sample container as shown.

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EXAMPLE
(ENLARGED FOR EASIER READING)

First Name	John
Last Name	Doe
Date of Birth (mm/dd/yy)	05/16/58
Date of Collection (mm/dd/yy)	03/20/16
Time of Collection (00:00)	08:15 AM AM

a.

a. Find the **Sample Label Card** included in the kit.

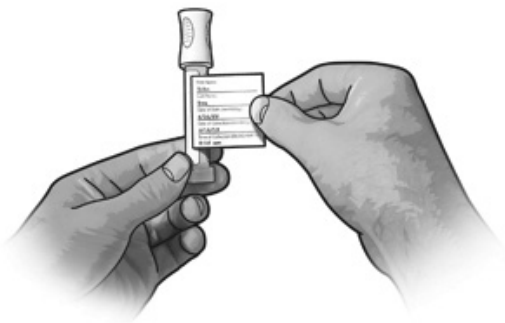
b.

b. Fill out **both** labels. **Print** the information in this order:

- Your first name (as it appears on the shipping label)
- Your last name
- Your birthdate (MM/DD/YY)
- The date you collected your stool sample (MM/DD/YY)
- The time you collected your stool sample; you must also circle AM or PM



- c. Peel the label away from the paper.



- d. Wrap one label around the tube.
- **The label can cover the existing label.**



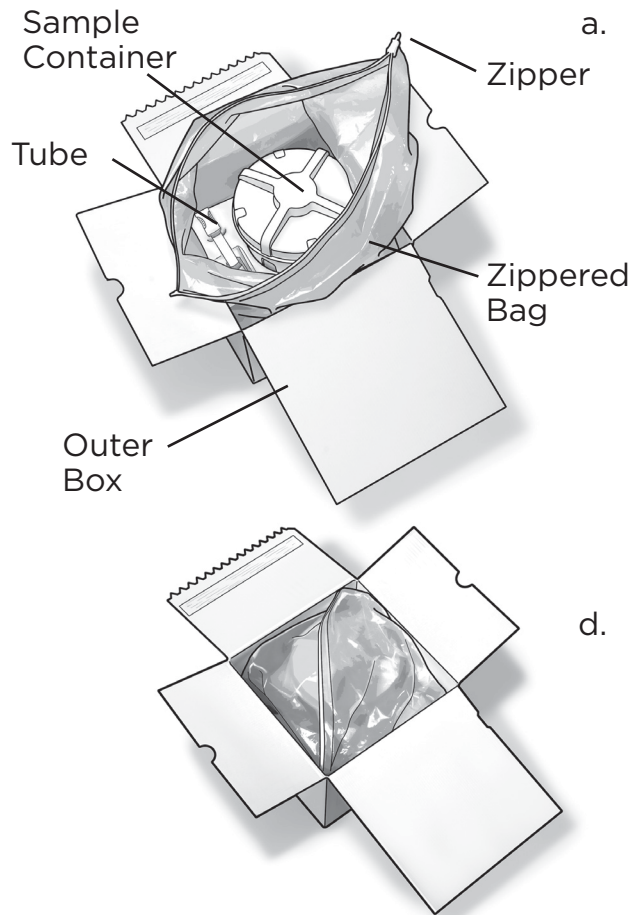
- e. Place one label on the lid of the sample container.

STEP 7: PREPARE YOUR SAMPLES FOR RETURN

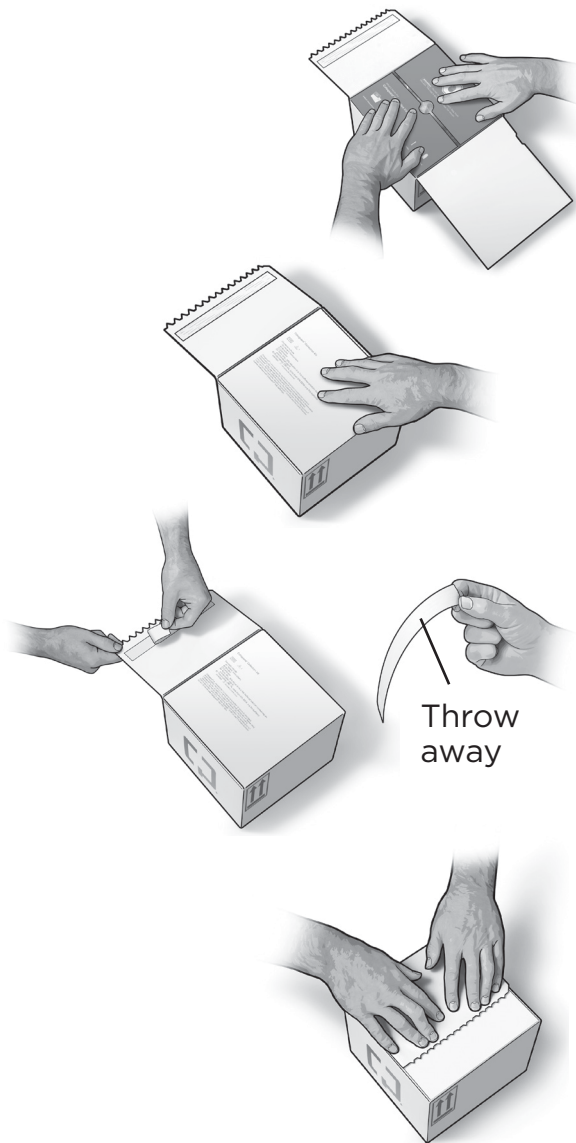
For best results, prepare your box on a hard, flat surface.

When you start, the zippered bag should be inside the box.

The white tray for holding the container and tube should be inside the bag.



- a. Place the tube and sample container into the tray inside the box.
- b. Fold the bag and push extra air out of the bag.
 - Too much air in the bag will make it hard to close the box.
- c. Slide the zipper across the top of the bag to close and seal the bag.
- d. Fold the bag until it fits inside the box.



- e. e. Fold the smaller flaps over the top of the box.
- f. f. Fold the long flap over the two smaller flaps.
- This is the white flap with the blue writing on it.
- g. g. Peel the paper backing off the tape on the box lid.
- Discard paper backing in garbage.
- h. h. Fold the box top over the other flaps and press down firmly to seal the box.
- i. i. Return your samples. Refer to your return instructions.

GLOSSARY

COLON:

A part of the human digestive system sometimes known as the large intestine.

COLORECTAL CANCER:

A disease of abnormal growths in the colon or rectum that, if left untreated, may spread throughout the body. Colon cancer generally develops over a number of years.

COLONOSCOPY:

A medical test where a flexible tube is placed into the colon, so the surface of the colon can be seen by a camera. Instruments can be placed through the tube to remove growths found on the colon wall.

DNA:

Deoxyribonucleic acid. Changes in the stool DNA (sDNA) can show your healthcare provider if there is cancer or a possibility of cancer.

HEMOGLOBIN:

A compound from blood. Blood or hemoglobin in the stool that cannot be seen by the naked eye is referred to as occult blood or occult hemoglobin.

NEOPLASIA:

A growth that is not normal.

PRECANCEROUS POLYP (ADENOMA):

A growth on the wall of the colon that may become cancer.

SYMBOLS USED ON THE COLOGUARD COLLECTION KIT

Collection of harmonized symbols used on labeling for the kit.



Lot
Number



Storage
Temperature



Catalog
Number



Expiration
Date



Manufacturer



Contains
Sufficient
for (n) Tests



In Vitro
Diagnostic Use




Caution

CLINICAL STUDY RESULTS

Cologuard was studied in a large clinical trial to determine the effectiveness of the test. The trial included more than 10,000 patients at 90 sites in the US and Canada. This study included adults ages 50-84. Each person in the study completed Cologuard and a fecal occult blood test before having a standard colonoscopy. The main purpose of the study was to find out the performance of Cologuard for finding cancer and precancer compared to a colonoscopy.

In the clinical study, Cologuard correctly detected 92% of colorectal cancers and 42% of advanced adenomas in the study population that had disease. The Cologuard test correctly gave a negative screening result for 87% of the study subjects that did not have colorectal cancer or advanced adenomas. In other words, 13% of people without cancer or precancer tested positive. The performance of Cologuard in adults ages 45-49 is estimated based on this large study.



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Exact Sciences intellectual property holdings and policies.

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